SECTION 5: 510(k) SUMMARY

K132145

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717- 487-1332
Fax Number: 717-849-4343

OCT 11 2013

Date Prepared: June 6, 2013

2. Device Name:

- Proprietary Name: MTM® Clear•Aligner
- Classification Name: Aligner, Sequential
- CFR Number: 872.5470
- Device Class: II
- Product Code: NXC

3. Predicate Device:

Product Name	510(K)	Clearance Date	Product Code	Company Name
MTM® Clear Aligner In-Office	K123925	May 30, 2013	NXC	DENTSPLY International

4. Description of Device:

MTM® Clear•Aligner is a system of plastic aligners fabricated in an orthodontic appliance laboratory. The formed aligners contain force points and spaces necessary for tooth movement by way of continuous gentle force. As the aligner is positioned on any particular tooth, the presence of the force points loads the polymeric shell material. The stored energy thus imparted into the elastomeric material of the aligner slowly dissipates over time as the bone underlying the tooth physiologically responds to the forces. After the entire series of aligners are produced by the MTM® Service Center for the prescribed case, they are shipped to the dental practitioner. Each individual aligner moves the patient's teeth in small increments from their original state to a final state.

5. Indications for Use:

MTM® Clear•Aligner is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental minor tooth movements (torque, tipping, rotation and bodily movement), MTM® Clear•Aligner sequentially positions teeth by way of continuous gentle force.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics:

MTM® Clear•Aligner has the same technological characteristics as the predicate device MTM® Clear Aligner In-Office in that a series of aligners are made by thermoforming commercially available DENTSPLY plastics. The series of aligners are then used to sequentially position teeth by way of continuous gentle force.

In both systems, the same DENTSPLY commercially available aligner materials are used. These plastics were originally cleared under K062828 (Mouthguard and Aligners materials). The MTM® Clear•Aligners are thermoformed by the MTM® Service Center (Orthodontic Laboratory) whereas the predicate MTM® Clear Aligner In-Office devices are thermoformed by the healthcare practitioner in-office.

Within the process of the subject device, the clinician submits impressions of the patient's teeth as well as a prescription form to the MTM® Clear Aligner Service Center. The MTM® Service Center uses standard commercially available dental software to create digital images and 3D overlays of the patient's dentition. These files are sent to the clinician along with a treatment plan for approval. Once approved by the clinician, the MTM® Service Center creates the aligners by thermoforming commercially available DENTSPLY plastics and sends them to the clinician. The clinician confirms the fit of the aligners upon delivery to the patient and monitors the patient's progress throughout treatment. In both systems, the healthcare practitioner is responsible for the treatment plan approval. Both systems utilize force points in order to cause minor tooth movement. The series of aligners created by both systems are used to sequentially position teeth by way of continuous gentle force and may be removed by the patient at any time.

Non-Clinical Performance Data:

The MTM® Clear•Aligner is composed of the identical, existing, commercially available DENTSPLY Aligner Materials used in the predicate device. All non-clinical performance data was included in the predicate submission, premarket notification K123925. No additional *in vitro* testing has been included to support the substantial equivalence of the MTM® Clear•Aligner.
A performance qualification of the commercially available software utilized in the processing steps of the subject MTM® Clear•Aligner has been included to support substantial equivalence.

Clinical Performance Data

A clinical evaluation was performed utilizing the predicate device MTM® Clear Aligner In-Office cleared under K123925 in order to collect safety and performance data regarding DENTSPLY aligner materials and force points to demonstrate the ability of the MTM® Clear•Aligner technology to achieve sequential incremental minor tooth movement (including torque, tipping, rotation and bodily translation), consistent with and fully supportive of the product's indications for use.

No new human clinical data has been included in this premarket notification to support the substantial equivalence of the MTM® Clear•Aligner.

Conclusion as to Substantial Equivalence:

MTM® Clear•Aligner moves teeth by way of continuous gentle force using a series of clear aligners and force points that follow the treatment plan prescribed by the clinician as does the predicate device MTM® Clear Aligner In-Office. Table 5.1 summarizes the comparison of the subject MTM® Clear•Aligner with the predicate MTM® Clear Aligner In-Office cleared in K123925).

Table 5.1 Substantial Equivalence Chart

	NEW DEVICE	PREDICATE DEVICE
	MTM® Clear•Aligner	**MTM® Clear Aligner In-Office (K123925)**
Product Code	NXC	NXC
Indication Statement	MTM® Clear•Aligner is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental minor tooth movements (torque, tipping, rotation and bodily movement), MTM® Clear•Aligner sequentially positions teeth by way of continuous gentle force.	MTM® Clear Aligner In-Office is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental minor tooth movements (torque, tipping, rotation and bodily movement), MTM® Clear Aligner sequentially positions teeth by way of continuous gentle force.
Material	Thermoformed co-polyester or co-polymer	Thermoformed co-polyester or co-polymer
Method of Application and Removal	The aligners can be removed and reinstalled by the patient for eating and cleaning.	The aligners can be removed and reinstalled by the patient for eating and cleaning.
Duration of Use	Aligners are most effective if worn 20 to 22 hours per day – and removed only for eating, brushing, and flossing. Each aligner is worn for about 2-3 weeks before being replaced by the next aligner in the sequence, until the final position of the patient's teeth is achieved.	Aligners are most effective if worn 20 to 22 hours per day – and removed only for eating, brushing, and flossing. Each aligner is worn for about 2-3 weeks before being replaced by the next aligner in the sequence, until the final position of the patient's teeth is achieved.
Mechanism of Action	MTM® Clear•Aligner incorporates the use of force points in order to exert force on the teeth while the aligner is being worn. This continuous force moves teeth from their original to final aligned position.	MTM® Clear Aligner In-Office incorporates the use of force points in order to exert force on the teeth while the aligner is being worn. This continuous force moves teeth from their original to final aligned position.
Software	Commercially available dental software is used to assist in the manufacture of the aligners.	Software is not utilized in the device or during the fabrication in the dental office.
OTC or Rx	Rx	Rx

MTM® Clear•Aligner is substantially equivalent to the predicate device MTM® Clear Aligner In-Office cleared under K123925 in that both systems have the same indications for use, same intended use, incorporate the same fundamental technological characteristics and they are composed of the same materials. Testing to demonstrate the acceptability of the commercially available software utilized in the treatment planning steps has been included to support substantial equivalence. Based on the similarities of the two devices, it is concluded that MTM® Clear•Aligner is substantially equivalent to the predicate device MTM® Clear Aligner In-Office.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 11, 2013

Dentsply International, Incorporated
Ms. Helen Lewis
Director of Corporate Regulatory Affairs
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Re: K132145
Trade/Device Name: MTM® Clear•Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: September 18, 2013
Received: September 18, 2013

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K132145

Device Name: MTM® Clear-Aligner

Indications for Use:

MTM® Clear-Aligner is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental minor tooth movements (torque, tipping, rotation and bodily movement), MTM® Clear-Aligner sequentially positions teeth by way of continuous gentle force.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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